

1 **CATHETER HAVING CIRCULAR ABLATION ASSEMBLY**

CROSS-REFERENCE TO RELATED APPLICATION

 This application is a continuation of Application Serial No. 10/118,680, filed
5 April 9, 2002, titled CATHETER HAVING CIRCULAR ABLATION ASSEMBLY, which
 claims the benefit of U.S. Provisional Patent Application No. 60/360,431, filed
 February 28, 2002, the disclosure of which is incorporated herein by reference.

FIELD OF THE INVENTION

10 The resent invention relates to an improved ablation catheter that is particularly useful for
 ablating in a tubular region of or near the heart.

BACKGROUND OF THE INVENTION

 Atrial fibrillation is a common sustained cardiac arrhythmia and a major cause of stroke.
15 This condition is perpetuated by reentrant wavelets propagating in an abnormal atrial-tissue
 substrate. Various approaches have been developed to interrupt wavelets, including surgical or
 catheter-mediated atriotomy. A common procedure involves ablating a lesion to interrupt the
 wavelets using one or more electrodes mounted on the distal end of a generally-straight catheter.
 This procedure works well, for example, when ablating a line of block in the atria. However, for
20 tubular regions in or around the heart, this procedure is less effective. For example, when the
 line of block is to be made about a circumference of the tubular region, it is difficult to
 manipulate and control the distal end of a straight catheter so that it effectively ablates about the
 circumference. Accordingly, a need exists for an improved catheter that is particularly useful for
 such applications.

25 **SUMMARY OF THE INVENTION**

 The present invention is directed to a catheter having a generally-circular ablation
 assembly mounted on its distal end that carries a tip electrode. In one embodiment, the catheter
 comprises an elongated flexible tubular catheter body having an axis and proximal and distal
30 ends. An ablation assembly is mounted at the distal end of the tubular body. The ablation

1 assembly has a preformed generally circular curve that is generally transverse to the axis of the catheter body comprising a flexible tubing having proximal and distal ends and carrying a tip electrode at its distal end. An electrode lead wire extends through the catheter body and into the ablation assembly and has a distal end connected to the tip electrode.

5 In use, the distal end of the catheter is inserted into the heart of a patient. At least a portion of the outer circumference of the generally circular curve is contacted with the inner circumference of the tubular region so that the tip electrode is in a first position in contact with tissue along the inner circumference. The tip electrode is used to ablate tissue at the first position. The ablation assembly can then be rotated so that the tip electrode is in a second
10 position in contact with tissue along the inner circumference different from the first position, and the tip electrode is used to ablate tissue at the second position. This procedure can be repeated to form a lesion of the desired length along the inner circumference. This design permits the user to have more control when ablating about a circumference of a tubular region in or around the heart, e.g., a pulmonary vein, the coronary sinus, the superior vena cava, or the pulmonary
15 outflow tract.

DESCRIPTION OF THE DRAWINGS

These and other features and advantages of the present invention will be better understood by reference to the following detailed description when considered in conjunction
20 with the accompanying drawings wherein:

FIG. 1 is a perspective view of an embodiment of the catheter of the invention;

FIG. 2 is a side cross-sectional view of a catheter body according to the invention, including the junction between the catheter body and the intermediate section;

FIG. 3 is a side cross-sectional view of the intermediate section, including the junction
25 between the intermediate section and the ablation assembly;

FIG. 4 is a schematic perspective view of an ablation assembly according to the invention;

FIG. 5 is a schematic perspective view of an alternative ablation assembly according to the invention;

30 FIG. 6 is a side view of the ablation assembly of FIG. 5;

1 FIG. 7 is a side cross-sectional view of the distal end of an ablation assembly according to the invention; and

 FIG. 8 is a perspective view of an alternative tip electrode according to the invention.

5 DETAILED DESCRIPTION

 In a particularly preferred embodiment of the invention, there is provided a catheter having an ablation assembly at its distal end. As shown in FIG. 1, the catheter comprises an elongated catheter body **12** having proximal and distal ends, an intermediate section **14** at the distal end of the catheter body, a control handle **16** at the proximal end of the catheter body, and
10 an ablation assembly **17** mounted at the distal end of the catheter to the intermediate section.

 With reference to FIG. 2, the catheter body **12** comprises an elongated tubular construction having a single, axial or central lumen **18**. The catheter body **12** is flexible, i.e. bendable, but substantially non-compressible along its length. The catheter body **12** can be of any suitable construction and made of any suitable material. A presently preferred construction
15 comprises an outer wall **20** made of polyurethane or PEBAX. The outer wall **20** comprises an imbedded braided mesh of stainless steel or the like to increase torsional stiffness of the catheter body **12** so that, when the control handle **16** is rotated, the intermediate section **14** of the catheter
10 will rotate in a corresponding manner.

 The outer diameter of the catheter body **12** is not critical, but is preferably no more than
20 about 8 french, more preferably about 7 french. Likewise, the thickness of the outer wall **20** is not critical, but is thin enough so that the central lumen **18** can accommodate a puller wire, one or more lead wires, and any other desired wires, cables or tubes. If desired the inner surface of the outer wall **20** is lined with a stiffening tube (not shown) to provide improved torsional stability. A particularly preferred catheter has an outer wall **20** with an outer diameter of from
25 about 0.090 inch to about 0.94 inch and an inner diameter of from about 0.061 inch to about 0.065 inch.

 The intermediate section **14** comprises a short section of tubing **22** having three lumens. The first lumen **30** carries one or more lead wires **50** or other wires discussed further below, the second lumen **32** carries a puller wire **64**, and the third lumen **34** carries a support member **24**.
30 The tubing **22** is made of a suitable non-toxic material that is preferably more flexible than the

1 catheter body **12**. A presently preferred material for the tubing **22** is braided polyurethane, i.e. polyurethane with an embedded mesh of braided stainless steel or the like. The size of each lumen is not critical, but is sufficient to house the lead wires, puller wire or support member.

5 The useful length of the catheter, i.e. that portion that can be inserted into the body excluding the ablation assembly **17**, can vary as desired. Preferably, the useful length ranges from about 110 cm to about 120 cm. The length of the intermediate section **14** is a relatively small portion of the useful length, and preferably ranges from about 3.5 cm to about 10 cm, more preferably from about 5 cm to about 6.5 cm.

A preferred means for attaching the catheter body **12** to the intermediate section **14** is 10 illustrated in FIG. 2. The proximal end of the intermediate section **14** comprises an outer circumferential notch **26** that receives the inner surface of the outer wall **22** of the catheter body **12**. The intermediate section **14** and catheter body **12** are attached by glue or the like.

15 If desired, a spacer (not shown) can be located within the catheter body between the distal end of the stiffening tube (if provided) and the proximal end of the intermediate section. The spacer provides a transition in flexibility at the junction of the catheter body and intermediate section, which allows this junction to bend smoothly without folding or kinking. A catheter having such a spacer is described in U.S. Patent No. 5,964,757, the disclosure of which is incorporated herein by reference.

20 At the distal end of the intermediate section **14** is the ablation assembly **17**, as shown in FIGs. 3 to 7. In the depicted embodiment, the ablation assembly **17** comprises the distal end of the support member **24** covered by a non-conductive covering **28**. In the embodiment of FIG. 4, the ablation assembly **17** comprises a generally straight proximal region **38** and a generally circular main region **39** that is generally transverse to the catheter body. The proximal region **38** is mounted on the intermediate section **14**, as described in more detail below, so that its axis is 25 generally parallel to the axis of the intermediate section. In this embodiment, the proximal region **38** is generally at the center of the generally circular main region **39**. The proximal region **38** preferably has an exposed length, i.e. not contained within the intermediate section **14**, ranging from about 3 mm to about 12 mm, more preferably about 3 mm to about 8 mm, still more preferably about 5 mm, but can vary as desired.

1 The generally circular main region **39** does not have to form a complete circle, but should
be at least about 180°, e.g. a semi-circle, more preferably at least about 270°, still more
preferably at least about 320°. In the preferred embodiment, the generally circular main region
39 forms at least a complete circle, e.g. is at least 360°. If desired, the generally circular main
5 region can comprise more than one loop or circle, so that it has, for example, a spiral or conical
shape. The generally circular main region **39** is generally transverse to the catheter body **12** and
intermediate section **14**, and preferably forms an angle with the catheter body ranging from about
80° to about 100°, more preferably about 90°. The generally circular main region **39** has an
outer diameter preferably ranging from about 2 mm to about 40 mm, more preferably from about
10 10 mm to about 25 mm, still more preferably from about 12 mm to about 20 mm, even more
preferably about 15 mm.

 In an alternative embodiment, as shown in FIGs. 5 and 6, the ablation assembly **17**
further comprises a generally straight distal region **40** that extends beyond the generally circular
main region **39**. In this embodiment, the proximal region **38** is at the side of the generally
15 circular main region **39**, as best shown in FIG. 6.

 The support member **24** is made of a material having shape-memory, i.e. that can be
straightened or bent out of its original shape upon exertion of a force and is capable of
substantially returning to its original shape upon removal of the force. A particularly preferred
material for the support member is a nickel/titanium alloy. Such alloys typically comprise about
20 55% nickel and 45% titanium, but may comprise from about 54% to about 57% nickel with the
balance being titanium. A preferred nickel/titanium alloy is nitinol, which has excellent shape
memory, together with ductility, strength, corrosion resistance, electrical resistivity and
temperature stability. The non-conductive covering **28** can be made of any suitable material, and
is preferably made of a biocompatible plastic such as polyurethane or PEBAX. If desired, the
25 support member **24** can be eliminated and the distal end of the non-conductive covering **28** can
be pre-formed to have the desired curve of the ablation assembly.

 A tip electrode **35** is mounted at the distal end of the ablation assembly **17** for ablating
tissue. As shown in FIG. 7, the tip electrode **35** has an exposed region **35a** and a stem **35b** that
extends into the non-conductive covering **28**. In the embodiment of FIG. 7, the tip electrode **35**
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1 has a generally cylindrical exposed region **35a** with an outer diameter approximately the same as the outer diameter of the non-conductive covering **28** by polyurethane glue or the like.

In an alternative embodiment, as shown in FIG. 8, the exposed region **35a** of the tip electrode has a bulb shape with a varying outer diameter wherein at least a portion of the exposed region extends beyond the outer circumference of the non-conductive covering **28**. It has been found that a catheter having a bulb-shaped tip electrode can provide better contact with the tissue based on the outward spring-like force exerted by the generally circular ablation assembly. Other tip electrode shapes will be apparent to one skilled in the art. For example, an asymmetrical tip electrode (not shown) could be provided where the side of the electrode that would be in contact with the tissue, i.e. on the outside of the ablation assembly, extends beyond the outer wall of the non-conductive covering **28** and the inner side of the tip electrode is generally even with the wall of the non-conductive covering.

An electrode lead wire **50** connects the tip electrode **35** to a suitable source of ablation energy (not shown), preferably radio frequency (RF) energy. The distal end of the lead wire **50** is soldered in a first blind hole **51** in the proximal end of the tip electrode **35**. The lead wire **50** extends between the non-conductive covering **28** and the support member **24**. The proximal end of the lead wire **50** is electrically connected to a suitable connector **37**, which is connected to the source of ablation energy as is known in the art. The lead wire **50** extends through the first lumen **30** of the intermediate section **14**, the central lumen **18** of the catheter body **12**, and the control handle **16**, and terminates at its proximal end in the connector **37**. In the depicted embodiment, the portion of the lead wire **50** extending through the central lumen **18** of the catheter body **12**, control handle **16** and proximal end of the intermediate section **14** is enclosed within a protective sheath **62** to prevent contact with other components within the lumen of the catheter body and in the handle. The protective sheath **62** can be made of any suitable material, preferably polyimide. The protective sheath **62** is anchored at its distal end to the proximal end of the intermediate section **14** by gluing it in the first lumen **30** with polyurethane glue or the like. As would be recognized by one skilled in the art, the protective sheath can be eliminated if desired.

A temperature sensor is provided for monitoring the temperature of the tip electrode **35**. Any conventional temperature sensor, e.g. a thermocouple or thermistor, may be used. In the

embodiment shown in FIG. 7, the temperature sensor comprises a thermocouple formed by an enameled wire pair. One wire of the wire pair is a copper wire **53**, e.g. a number 40 copper wire. The other wire of the wire pair is a constantan wire **54**. The wire **53** and **54** of the wire pair are electrically isolated from each other except at their distal ends where they are twisted together, covered with a short piece of plastic tubing **55**, e.g. polyimide, and covered with epoxy. The plastic tubing **55** is then attached in a second blind hole **56** of the tip electrode **35**, by polyurethane glue or the like. Alternatively, the wires **53** and **54** can be soldered into the second blind hole **56** or otherwise attached to the tip electrode **35**. The wires **53** and **54** extend through the first lumen **30** in the intermediate section **14** and through the central lumen **18** of the catheter body **12** along with the lead wire **50**. The wires **53** and **54** then extend out through the control handle **16** and to a connector (not shown) connectable to a temperature monitor (not shown). Preferably, the wires **53** and **54** extend through the protective sheath **62** in the catheter body **12**.

Additionally, a safety wire **57** is provided to further secure the tip electrode **35** to the ablation assembly **17** and assure that the tip electrode does not fall off in the patient's body. The safety wire is preferably a metal wire having its distal end soldered in a third blind hole **58** in the tip electrode **35** and its proximal end soldered or otherwise attached in the control handle **126**. In the depicted embodiment, the safety wire **57** extends through the first lumen **30** in the intermediate section **14** and through the central lumen **18** of the catheter body **12** along with the lead wires **50** and thermocouple wires **53** and **54**. Other arrangements for attaching the safety wire can be provided, as would be recognized by one skilled in the art, or the safety wire can be eliminated.

If desired, one or more ring electrodes (not shown) can be mounted on the non-conductive covering **28** of the generally circular main region **39** of the ablation assembly **17**. Such ring electrodes might be desirable, for example, for mapping the region to be ablated before ablation begins or after ablation to assure that the lesions blocked the electrical activity as desired. A description of a catheter including such ring electrodes is described in U.S. Patent Application No. 09/551,467, entitled "Catheter Having Mapping Assembly," the entire disclosure of which is incorporated herein by reference. If desired, additional ring electrodes (not shown) could be mounted elsewhere along the ablation assembly **17** and/or intermediate section **14**.

1 The junction of the intermediate section **14** and ablation assembly **17** is shown in FIG. 3.
The non-conductive covering **28** is attached to the tubing **22** of the intermediate section by glue
or the like. The support member **24** extends from the third lumen **34** into the non-conductive
covering **28**. The proximal end of the support member **24** terminates a short distance within the
5 third lumen **34**, approximately 5 mm, so as not to adversely affect the ability of the intermediate
section **14** to deflect. However, if desired, the proximal end of the support member **24** can
extend into the catheter body **12**.

 The lead wires **50**, thermocouple wires **53** and **54** and safety wire **57** extend through the
first lumen **30** of the intermediate section **14**, through the central lumen **18** of the catheter body
10 **12**, and the control handle **16**, and terminate at their proximal end in the connector **37**. As noted
above, the portion of the wires extending through the central lumen **18** of the catheter body **12**,
control handle **16** and proximal end of the intermediate section **14** are enclosed within a
protective sheath **62**, which can be made of any suitable material, preferably polyimide. The
protective sheath **62** is anchored at its distal end to the proximal end of the intermediate section
15 **14** by gluing it in the first lumen **30** with polyurethane glue or the like.

 The puller wire **64** is provided for deflection of the intermediate section **14**. The puller
wire **64** extends through the catheter body **12**, is anchored at its proximal end to the control
handle **16**, and is anchored at its distal end to the intermediate section **14**. The puller wire **64** is
made of any suitable metal, such as stainless steel or Nitinol, and is preferably coated with
20 Teflon[®] or the like. The coating imparts lubricity to the puller wire **64**. The puller wire **64**
preferably has a diameter ranging from about 0.006 to about 0.010 inch.

 A compression coil **66** is situated within the catheter body **12** in surrounding relation to
the puller wire **64**, as shown in FIG. 2. The compression coil **66** extends from the proximal end
of the catheter body **12** to the proximal end of the intermediate section **14**. The compression coil
25 **66** is made of any suitable metal, preferably stainless steel. The compression coil **66** is tightly
wound on itself to provide flexibility, i.e. bending, but to resist compression. The inner diameter
of the compression coil **66** is preferably slightly larger than the diameter of the puller wire **64**.
The Teflon[®] coating on the puller wire **64** allows it to slide freely within the compression coil **66**.
The outer surface of the compression coil is covered by a flexible, non-conductive sheath **58**, e.g.
30 made of polyimide tubing.

1 The compression coil **66** is anchored at its proximal end to the outer wall **20** of the catheter body **12** by proximal glue joint **70** and at its distal end to the intermediate section **14** by distal glue joint **72**. Both glue joints **70** and **72** preferably comprise polyurethane glue or the like. The glue may be applied by means of a syringe or the like through a hole made between the
5 outer surface of the catheter body **12** and the central lumen **18**. Such a hole may be formed, for example, by a needle or the like that punctures the outer wall **20** of the catheter body **12** which is heated sufficiently to form a permanent hole. The glue is then introduced through the hole to the outer surface of the compression coil **66** and wicks around the outer circumference to form a glue joint about the entire circumference of the compression coil.

10 The puller wire **64** extends into the second lumen **32** of the intermediate section **14**. Preferably, the puller wire **64** is anchored at its distal end to the distal end of the intermediate section **14**, as shown in FIG. 3. Specifically, a T-shaped anchor is formed, which comprises a short piece of tubular stainless steel **80**, e.g. hypodermic stock, which is fitted over the distal end of the puller wire **64** and crimped to fixedly secure it to the puller wire. The distal end of the
15 tubular stainless steel **80** is fixedly attached, e.g. by welding, to a cross-piece **82** formed of stainless steel ribbon or the like. The cross-piece **82** sits beyond the distal end of the second lumen **32**. The cross-piece **82** is larger than the lumen opening and, therefore, cannot be pulled through the opening. The distal end of the second lumen **32** is then filled with glue or the like, preferably polyurethane glue. Within the second lumen **32** of the intermediate section **14**, the
20 puller wire **64** extends through a plastic, preferably Teflon[®], puller wire sheath (not shown), which prevents the puller wire **64** from cutting into the wall of the intermediate section **14** when the intermediate section is deflected.

 Longitudinal movement of the puller wire **64** relative to the catheter body **12**, which results in deflection of the intermediate section **14**, is accomplished by suitable manipulation of
25 the control handle **16**. Examples of suitable control handles for use in the present invention are disclosed, for example, in U.S. Patent Nos. Re 34,502 and 5,897,529, the entire disclosures of which are incorporated herein by reference.

 In use, a suitable guiding sheath is inserted into the patient with its distal end positioned at a desired mapping location. An example of a suitable guiding sheath for use in connection
30 with the present invention is the Preface[™] Braided Guiding Sheath, commercially available from

1 Biosense Webster, Inc. (Diamond Bar, California). The distal end of the sheath is guided into one of the atria. A catheter in accordance with the present invention is fed through the guiding sheath until its distal end extends out of the distal end of the guiding sheath. As the catheter is fed through the guiding sheath, the ablation assembly **17** is straightened to fit through the sheath.

5 Once the distal end of the catheter is positioned at the desired mapping location, the guiding sheath is pulled proximally, allowing the deflectable intermediate section **14** and ablation assembly **17** to extend outside the sheath, and the ablation assembly **17** returns to its original shape. The ablation assembly **17** is then inserted into a pulmonary vein or other tubular region (such as the coronary sinus, superior vena cava, or inferior vena cava) so that the outer

10 circumference of the generally circular main region **39** of the assembly is in contact with a circumference inside the tubular region and the tip electrode **35** is generally in contact with the tissue.

The circular arrangement of the ablation assembly **17** provides a stable mechanism for keeping the tip electrode **35** in a desired location for ablation. To ablate a circumferential lesion

15 in the tubular region, the user rotates the ablation assembly **17** by rotating the control handle **16** and applies ablation energy through the tip electrode **35** at adjacent points along the circumference. The design of the ablation assembly permits the user to more easily ablate about a circumference compared to using a tip electrode on a straight catheter, where it is more difficult to accurately move the tip electrode about the circumference of the tubular region.

20 As will be recognized by one skilled in the art, it is easier to turn the ablation assembly in a direction such that the tip electrode is being pulled rather than pushed. For example, in the embodiments depicted in FIGs. 4 and 5, where the ablation assemblies are formed in a clockwise direction, it is preferable to turn the assemblies in a counterclockwise direction. Accordingly, if desired, an arrow or other indicator (not shown) can be included on the handle or proximal end

25 of the catheter body to indicate to the user the preferred direction for rotating the ablation assembly in the body.

If desired, two or more puller wires can be provided to enhance the ability to manipulate the intermediate section. In such an embodiment, a second puller wire and a surrounding second compression coil extend through the catheter body and into an additional off-axis lumen in the

30 intermediate section. The first puller wire is preferably anchored proximal to the anchor location

1 of the second puller wire. Suitable designs of catheters having two or more puller wires,
including suitable control handles for such embodiments, are described, for example, in U.S.
Patent Nos. 6,123,699, 6,171,277, 6,183,435, 6,183,463, 6,198,974, 6,210,407, and 6,267,746,
the disclosures of which are incorporated herein by reference.

5 Alternatively, a second puller wire (not shown) can be included to alter the diameter of
the distal end of the ablation assembly. Such an arrangement is generally described in U.S.
Patent No. 5,626,136, the disclosure of which is incorporated herein by reference. The above-
referenced control handles could be used to manipulate the second puller wire.

The preceding description has been presented with reference to presently preferred
10 embodiments of the invention. Workers skilled in the art and technology to which this invention
pertains will appreciate that alterations and changes in the described structure may be practiced
without meaningfully departing from the principal, spirit and scope of this invention.

Accordingly, the foregoing description should not be read as pertaining only to the
precise structures described and illustrated in the accompanying drawings, but rather should be
15 read consistent with and as support to the following claims which are to have their fullest and
fairest scope.